PATENT
459-226P

IN THE U.S. PATENT AND TRADEMARK OFFICE

APPLICANT: ANDERSEN, Peter et al.

SERIAL NO.: 08/981,021 GROUP: 1642

FILED: March 20, 1998 EXAMINER: G. Bansal

FOR: RECOMBINANT ANTIBODIES FROM A PHAGE DISPLAY LIBRARY, DIRECTED AGAINST A PEPTIDE-MHC COMPLEX

DECLARATION SUBMITTED UNDER 37 C.F.R. § 1.132

Honorable Commissioner
Of Patents and Trademarks
Washington, D.C. 20231

COPY

Sir:

I, Dr. Soren Buus of Stenmaglevej 29, DK-2700 Brønshøj, Denmark, do hereby declare the following:

I have attached a copy of my curriculum vitae to this Declaration.

I am a coinventor in the above-identified application, Serial No. 0/981,021

I have read and understand the subject matter of the Office Action of May 23, 2000.

The following comments are offered in support of the patentability of the instant invention.

The technique chosen by any scientist will depend entirely upon one's experience. That is, if one can do phage display, one will not attempt hybridomas and vice versa (if one can do neither, one is most likely to -and will be advised to- give up).

Thus, it only makes sense to compare an expert in hybridomas technology with an expert in phage display technology. The speed and efficiency of the current invention and the invention presented in the Duc et al. publications (1993 and WO-A-91/12332) can be compared as noted below.

If using immunized animals:

Immunization will take anywhere from 3 months to 12 months. For hybridomas, it is more likely to require prolonged immunization to get strong signal and little background since, as a screening technology it is demanding in terms of immunization quality. Derivation of the Specificity This will take about one (1) month with the phage display technology. In the same amount of time, one will only have started to screen if using the hybridomas technology and it will take another two (2) to four (4) months to go through testing and subcloning. As a screening technology, the hybridoma technology is demanding in terms of large scale testing to search for the desired specificity.

Note that if one is using giga/tera-libraries for phage display, one does not need immunization and the derivation of specificity should take some two (2) weeks. These libraries, however, are even more technologically demanding. A paper on this has just been published (Chames et al., 5 July 2000, PNAS 97: 7969).

Thus, the speed and efficiency can be estimated:

Hybridoma technology: Time of immunization + 3-5 months, low efficiency

Phage display from "immunized" libraries: time of immunization + 1 month, intermediate efficiency.

Phage display from tera-libraries: 2 weeks, high efficiency

The current invention describes the use of tera-libraries. Finally, we wish to point out that, to our knowledge, the Chames et al. paper (5 July 2000) was the first publication on this topic, attesting to the non-obviousness of the current invention.

Application No. 08/981,021

The undersigned hereby declares that all statements made herein based upon knowledge are true, and that all statements made based upon information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED 6 October 2000

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